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## THREE ARIZONA RESIDENTS, FOUR COMPANIES, INDICTED FOR FRAUDULENT DRUG DISTRIBUTION SCHEME

PHOENIX, Ariz. – A federal grand jury in Phoenix returned a 31-count indictment on Tuesday, January 15, 2008 against Timothy K. Isaac, 46, of Avondale, Ariz.; Bryan P. Gillette, 46, of Scottsdale, Ariz.; and Laura C. Gillette, 45, of Scottsdale, Ariz., for conspiracy; introducing misbranded drugs and foods into interstate commerce; failing to register an establishment in which drugs were manufactured; mail and wire fraud; and money laundering. Four local companies owned and/or operated by Isaac also were named in the indictment: Ultra Health Laboratories, Inc.; Ultra Health Products, Inc.; Bionate International, Inc.; and Johnston-Keay Laboratories, Inc. The Gillettes were taken into custody this morning and are expected to appear in federal court at 3:00 p.m. today for their initial appearance. A summons was issued to Isaac; he will be arraigned on these charges at a later date.

The indictment alleges that the defendants manufactured and widely marketed, both through distributors and retailers and directly to consumers, a sexual enhancement product called Vinarol. Although they claimed that Vinarol was an all-natural herbal dietary supplement, the defendants knew that, in fact, Vinarol was made with sildenafil citrate, the active ingredient in Pfizer Inc.'s Viagra. The defendants told consumers that there were no side effects associated with Vinarol and sold it without requiring a doctor's visit or prescription, even though the Food and Drug Administration (FDA) allows sildenafil citrate to be dispensed only via a doctor's prescription because of its potentially deadly interactions with many commonly-taken medications.

According to the indictment, the defendants smuggled the sildenafil citrate into the U.S. from China by mixing it with herbal products to mask its color and texture and by falsely describing it on U.S. Customs Service forms and other entry documents. The defendants also fraudulently failed to register as a drug manufacturer with FDA in order to circumvent strict pre- and post-market regulatory safeguards designed to ensure that drugs sold in the United States are safe and effective. The scheme generated revenues for defendants of approximately \$7,500,000.

The maximum penalties are as follows: Conspiracy, five years in prison, a \$250,000 fine or both; introducing misbranded drugs and foods into interstate commerce and failing to register an establishment in which drugs are manufacture, three years in prison, a \$250,000 fine, or both; mail and wire fraud, 20 years in prison, a \$250,000 fine, or both; and money laundering, 20 years in prison, a \$500,000 fine, or both. In determining an actual sentence, the assigned judge will consult the U.S. Sentencing Guidelines, which provide appropriate sentencing ranges. The judge, however, is not bound by those guidelines in determining a sentence.

An indictment is simply the method by which a person is charged with criminal activity and raises no inference of guilt. An individual is presumed innocent until competent evidence is presented to a jury that establishes guilt beyond a reasonable doubt.

The investigation preceding the indictment was conducted by the Food and Drug Administration's Office of Criminal Investigations with assistance from U.S. Immigrations and Customs Enforcement. The prosecution is being handled by Peter Sexton, Assistant U.S. Attorney, and Steven Tave, Special Assistant U.S. Attorney, District of Arizona, Phoenix.

CASE NUMBER: CR 08-0036-PHX-PGR RELEASE NUMBER: 2008-005(Isaac, et al)

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